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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,957	01/11/2001	Robert N. Hanson	ZAA-011.01	9648

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EXAMINER

BAKER, MAURIE GARCIA

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 04/21/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/758,957

Applicant(s)

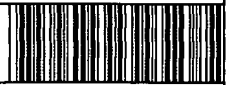
Hanson et al

Examiner

Maurie G. Baker

Art Unit

1639



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 27, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15, 17-20, 22, 24-27, 29, 31-34, 36, 38-41, and 43 is/are pending in the application.
- 4a) Of the above, claim(s) 29, 31-34, 36, and 38-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15, 17-20, 22, 24-27, and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

Please note: The number of Art Unit 1627 has been changed to 1639. Please direct all correspondence for this case to **Art Unit 1639**.

1. The Response filed January 27, 2003 (Paper No. 11) is acknowledged. Claims 15, 22, 29, 36 and 43 were amended and claims 1-14, 16, 21, 23, 28, 30, 35, 37, 42 and 44-54 were cancelled. Therefore, claims 15, 17-20, 22, 24-27, 29, 31-34, 36, 38-41 and 43 are pending.

Election/Restriction

2. As noted in the previous action, claims 21, 28 and 29-42 do not read on the elected species. As there is still no allowable generic claim, pending claims 29, 31-34, 36, and 38-41 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected species.

3. Therefore, claims 15, 17-20, 22, 24-27 and 43 (in part) are examined on the merits in this action.

Status of Objections

4. The objection to the disclosure is withdrawn in view of applicant's amendments thereto. The claim objections are also withdrawn in view of applicant's amendments.

Status of Rejections

5. The previous rejections under 35 USC 112, first paragraph, 35 USC 102 and 35 USC 102/103 are withdrawn in light of applicant's claim amendments. Also, the rejections under 35 U.S.C. 112, second paragraph are withdrawn *in part*. However, new rejections necessitated by applicants claim amendments are set forth.

***Maintained Rejections
Claim Rejections - 35 USC § 112***

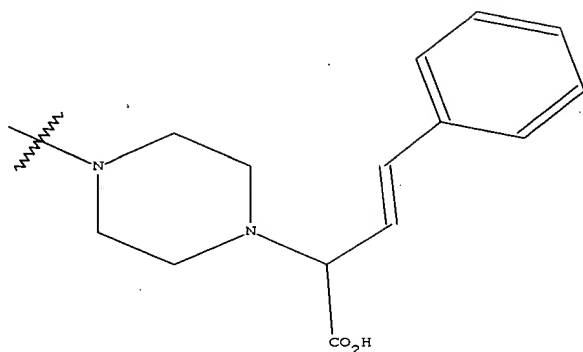
6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

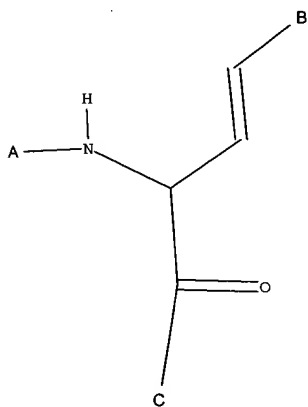
7. Claims 20 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Withdrawn

B. The recitations in claims 20 and 27 of "wherein said pharmacophoric units are selected from the group consisting of D-1 agonist, D-2 agonist , D-3 agonist ... and dopamine transporter inhibitor" are deemed to be highly confusing and indefinite when the claims are interpreted in light of the specification. The elected species of "polypharmacophore" (Response, page 2, top), is the following structure (shown in part) and found in Figure 9:



The elected species of “pharmacophoric unit” is dopamine transporter inhibitor. However, when compared to the “polypharmacophore” defined in claims 29-42 comprising the formula (III) {and similarly (IIIA)} where “at least two of A, B or C comprise a pharmacophore”:



it is clear that moieties such as phenyl and –OH fall within the definition of “pharmacophore”. It is completely confusing how moieties such as these would also fit the limitation of dopamine transporter inhibitor. It is unclear how the assessment of the activity of each of the pharmacophores is determined (e.g. how is –OH determined to be a dopamine transporter inhibitor?).

Response to Arguments

8. Applicant's arguments filed January 27, 2003 have been fully considered but are not found persuasive. The examiner's rationale is set forth below.

9. Applicant argues that in light of the claim amendments, the claims are now definite. The examiner respectfully disagrees. It is still highly unclear and confusing how moieties such as the now claimed aryl, aralkyl, ether, amido and/or CO₂H (i.e. instant R₁, R₂ and R₃) would also fit the limitation of dopamine transporter inhibitor (or any of the other functions listed in the claims).

10. Note the following from MPEP 2173.02: If the scope of the invention sought to be patented cannot be determined from the language of the claims with a reasonable degree of certainty, a rejection of the claims under 35 U.S.C. 112, second paragraph is appropriate. *In re Wiggins*, 488 F.2d 538, 179 USPQ 421 (CCPA 1973). For these reasons, the above rejection is maintained.

***New Rejections --- Necessitated by Amendment
Claim Rejections - 35 USC § 112***

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 15, 17-20, 22, 24-27 and 43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed does not provide support for the invention as now claimed. Applicant's amendment asserts that no new matter has been added; however, the Response does not point to any specific support for the newly added generic structures (i.e. formula II/IIA) and these generic structures do not appear anywhere in the instant specification. The specification as originally filed includes only three specific structures that would read on the presently claimed generic (i.e. Figure 9). This is deemed to be insufficient support for the newly recited generics which encompass wide variety of compounds outside of those presented in Figure 9.

Also, it is unclear what is the specific structure of the compounds of formula II/IIA because the R₁, R₂ and R₃ moieties are *incompletely defined* (see rejection under 35 USC 112, second paragraph below). For example, if R₁ is a moiety such as "amido" or "ester", what is the actual structure of such a group? The same is true for recitations such as "amine" and "ether". That is, denoting the group as "amido" (for example) does not fully define what amide is being referred to. Thus it is additionally unclear that applicant has support for such compounds. Moreover, there is absolutely no support whatsoever for the newly recited generic

structures containing any of the claimed "modifier units" attached thereto. Lastly, there does not appear to be support for the recited "modifier units" either. The moieties listed appear as "targeting agents" in the instant specification.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 15, 17-20, 22, 24-27 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Independent claims 15 and 22 have been amended to recite a generic structure with R_1 , R_2 and R_3 groups. It is unclear what is the specific structure of the compounds of formula II/IIA because the R_1 , R_2 and R_3 moieties are *incompletely defined*. For example, if R_1 is a moiety such as "amido" or "ester", what is the actual structure of such a group? The same is true for recitations such as "amine" and "ether". That is, denoting the group as "amido" (for example) does not fully define what amide is being referred to. This adds considerable confusion to the claims, making it impossible to determine the metes and bounds thereof. Thus, claims 15 and 22 and all claims dependent thereon are indefinite.

B. Claims 20 and 27 recite "pharmacophoric unit". There is insufficient antecedent basis for this terminology in the claims. Claims 15 and 22 (on which claims 20 and 27 depend) no longer recite this terminology.

Status of Claims/Conclusion

15. No claims are allowed.


16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
April 14, 2003



MAURIE GARCIA BAKER PH.D.
PRIMARY EXAMINER